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INDUSTRY GUIDANCE DOCUMENT ON APPLICATION OF THE FACILITY CHANGE PROCESS

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1. INTRODUCTION

1.1 Purpose of the Industry Guidance

The *Industry Guidance Document on Application of the Facility Change Process* will assist a Part 70 licensee in use of the 10 CFR 70.72 facility change process. This new change mechanism allows the licensee to make certain changes to the facility and its processes without prior NRC pre-approval. This guidance outlines a procedure to use the risk of a proposed change, as established by internal procedures, the Configuration Management System or ISA analysis, to determine if the proposed change requires NRC pre-approval and a license amendment, or whether the licensee may make the change with only written notification to the NRC following its implementation.

Subpart H of 10 CFR 70 requires designation as an Item Relied On For Safety (IROFS) any safety control (or control system) that is installed to prevent or mitigate an intermediate- or high-risk accident sequence whose consequences could exceed the performance requirements of 10 CFR 70.61. IROFS for such intermediate- or high-risk accident sequences are listed in the ISA Summary. Changes to such IROFS listed in the ISA Summary stand a greater chance of requiring NRC pre-approval, particularly if the type, number or robustness of individual IROFS is to be changed.

This document provides guidance in three areas:

(1) **Configuration Management System**: what are the core elements of a configuration management system and how is it used to evaluate proposed facility changes?

(2) **Pre-Approval Need**: how to determine if NRC pre-approval of a change is required?

(3) **Reporting Requirements**: what information must be reported to the NRC on facility changes and at what frequency?

Guidance in this document will facilitate compliance with the requirements of 10 CFR 70.72. Adoption of this guidance will provide consistency in the content, style and completeness of applications submitted to the NRC and should, therefore, facilitate and expedite NRC staff reviews.

1.2 Relation of Industry Guidance to NUREG-1520

Chapter 11 of NUREG-1520 ('*Standard Review Plan for the Review of a License Application for a Fuel Cycle Facility*') provides guidance on use of Configuration Management (¶11.3.1) and Records Management (¶11.3.7) as management measures applied to IROFS.

The *Industry Guidance Document on Application of the Facility Change Process* provides a licensee with guidance on how these two functions are to be used in support of the 10 CFR 70.72 change process – and not just as a management measure for IROFS identified in the ISA Summary. It explains how the licensee should decide whether a proposed change requires NRC pre-approval and how such changes should be reported on a quarterly or annual basis to the NRC.

1.3 Change Process Regulations

The 10 CFR 70.72 facility change process regulations are reproduced in Appendix A.

2. ELEMENTS OF THE CHANGE PROCESS

The three steps in the facility change process are briefly summarized in this Chapter 2. More detailed information for each is provided in Chapters 3-5.

2.1 Configuration Management System

The facility Configuration Management System is used to evaluate each proposed change to a facility system [10 CFR 70.72(a)] and to predict performance under normal operating conditions and potential process upsets. The ISA is updated taking the proposed change into consideration to identify any new accident sequences, any adverse impacts on existing IROFS and any changes that should be made to the ISA Summary.

An effective Configuration Management System for evaluating facility system changes will generally have the following five elements:

- policy statement
- organizational structure
- methods to evaluate proposed changes
- documentation requirements
- change implementation

Although the NRC is unlikely to examine a licensee's Configuration Management System as part of a facility change request, it will seek continuing assurance that a well structured, robust program, consistent with the intent of 10 CFR 70.61(d) and NUREG-1520 Chapter 11 is in place. The core elements of a Configuration Management System used for change analysis are presented in this Chapter 3 guidance.

2.2 Change Approval Options

The impacts of a proposed change on health and safety or on the control of licensed material must first be assessed. Section(s) of the facility ISA that will be impacted must then be identified and replacement pages(s) drafted for inclusion in the ISA once the proposed change is implemented. Finally, the licensee must decide whether or not the proposed change requires NRC-approval. If NRC pre-approval is considered necessary, the licensee must proceed to file an application for a license amendment by means of the procedure referenced in 10 CFR 70.34. Otherwise, the licensee may proceed to evaluate and implement the change in accordance with its internal procedures.

NRC pre-approval will generally be required if a substantive change is made to an IROFS, if the change could result in a new accident sequence that has not been previously analyzed in the ISA or if any change is made to an IROFS that is the sole IROFS preventing an accident.

2.3 Records and NRC Reporting Requirements

The licensee must retain internal records of all analyses undertaken in support of an implemented change [10 CFR 70.62(f)]. Additionally, annual reports must be submitted to the NRC for all changes for which NRC pre-approval was not required [10 CFR 70.62(d)]. Annual *Facility Change Reports* are required to report all changes important to health and safety and the control of licensed material made to the facility during a calendar year. This annual report would include, for example, all changes made to IROFS during the year.

3. CONFIGURATION MANAGEMENT SYSTEM

3.1 Introduction

A licensee must establish a Configuration Management System to evaluate, implement and track additions or changes to facility systems [10 CFR 70.72(a)]. A Configuration Management System establishes a formal review process to analyze new equipment, systems, procedures and components (or modifications to existing equipment, systems, procedures and components), in order to reliably predict performance under normal operating conditions and potential process upsets. It ensures consistency among the facility design, physical configuration and facility documentation, particularly as applied to IROFS. The system must, through written procedures, define the review and approval process to assure that impacted systems will continue to meet or exceed regulatory specification requirements of the ISA baseline safety assessment.

Configuration management is one of eight management measures a licensee must apply to IROFS to ensure their availability and reliability when required [10 CFR 70.4 and 70.62(d)]. When applied to IROFS, the Configuration Management System is also used to ensure that the ISA, ISA Summary and process safety information are updated to reflect the current facility process configurations.

A licensee will generally not be required to describe its Configuration Management System in support of an application for a facility change. However, the NRC will seek assurances that the licensee does have in place a well structured and robust system that is consistent with the intent of 10 CFR 70.61(d). This guidance and NUREG-1520 Chapter 11 outline the core elements of an acceptable Configuration Management System.

3.2 System Core Elements

The Configuration Management System should include the following five elements:

(1) ***Policy Statement***: statement of the purpose and function of the Configuration Management System, explanation of how it will ensure consistency among the facility design, physical configuration and facility documentation, applicability to facility systems (including IROFS), principal system activities, commitment to use written procedures, commitment to periodically review the system effectiveness and to implement improvements, as required.

(2) ***Organizational Structure***: statement of the organizational structure of the Configuration Management System, principal engineering and management

staff positions and personnel assignments, reporting mechanisms to facility and engineering management

(3) ***Evaluation of Changes***: explanation of the principal steps in applying the Configuration Management System to evaluate a change. These steps include the following:

- internal procedure(s) to initiate and track a proposed change, assignment of responsible individual(s)
- change description (clear description of the technical basis of the change, identification of process involved and whether the impacted process(es) are high- or intermediate-risk, changes anticipated, duration of the change (permanent or temporary), potential impacts on IROFS, health and safety, compliance with appropriate regulatory requirements, conformance with regulatory and license commitments, etc.)
- procedures for preliminary assessment and categorization of the proposed change ('minor' or 'significant' designation)
- review procedures for significant changes: engineering and specialist reviews in the following disciplines, as appropriate:
    - licensing
    - nuclear criticality safety
    - radiation protection
    - industrial health and safety
    - environmental protection engineering
    - security
    - nuclear materials control and accounting
- ISA update (new accident sequence or re-evaluation of previously evaluated accident sequence, ISA methodology used, assignment of personnel expert in appropriate disciplines such as fire safety, nuclear criticality safety, methodology, etc.)
- impacts on design bases (comparison to ISA results) and impacts on worker and public health and safety and the control of licensed material
- supporting changes required (operating procedures, training)
- change approval (authorized personnel and incorporation of limitations)

(4) ***Documentation***: description of methods to establish and control documentation and to ensure consistency among facility physical configuration and documentation (engineering drawings, PI&D, etc.), incorporation of changes to the facility baseline design basis, procedures to update the ISA and ISA Summary

(5) ***Change Implementation***: description of the key steps in implementing the change (final engineering review, issuance of work orders, contractor supervision, testing, physical reviews by criticality safety personnel (fissile material), start-up and acceptance

4. CHANGE APPROVAL OPTIONS

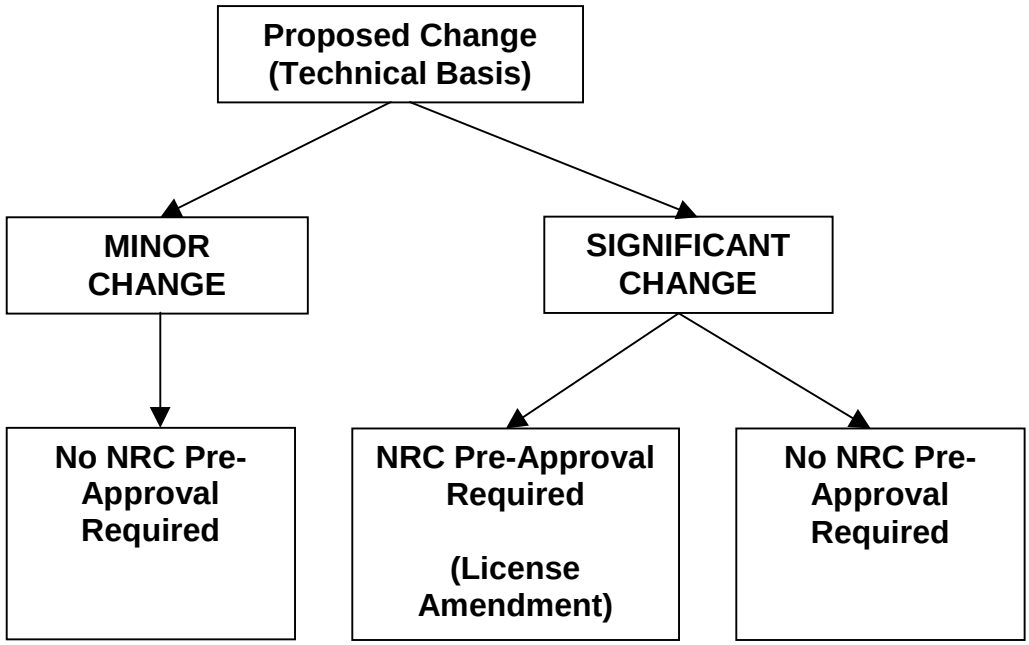
4.1 Available Approval Options

Modifications or additions to facilities, processes, procedures and equipment must be evaluated and approved before a change is made. The licensee should first use the facility's internal procedures to review the safety-significance and risk of a change and to establish whether the change is 'minor' or 'significant'. 'Minor' changes, as defined by such internal procedures, should generally be approved by the change originators and engineering staff evaluators without consideration of NRC pre-approval. 'Significant' changes will generally require a more formal, structured review including consideration of updates of the ISA and of the input from specialized engineering disciplines (e.g. nuclear criticality safety, radiation protection, fire safety, etc.). 'Significant' changes, as defined by internal procedures, must be approved by evaluations and recommendations of the engineering evaluators – perhaps under the auspices of a formal organization such as a Facility Change Committee or Change Review Board. Members of this organization must decide whether or not NRC pre-approval of the change is required.

Three options are, therefore, available for approval of a proposed change:

- **Minor Change** – Internal approval (only) required
- **Significant Change** – NRC pre-approval required
- **Significant Change** – Internal approval (only) required

These change approval options are illustrated in the following figure.



4.1.1 Minor Changes

Minor changes are those that the licensee establishes to have little safety significance and that can be implemented following internal licensee procedures. Examples of minor changes would include:

(1) minor change in an operating procedure (e.g. small adjustment in an operating parameter range or value, change reflecting different positioning of a piece of equipment, a change in preventive maintenance procedure or frequency)
(2) minor adjustment of a safety control applied to an accident sequence that has extremely low probability of exceeding the 10 CFR 70.61 performance criteria (i.e. accident sequence is not included in ISA Summary)
(3) addition of redundant IROFS
(4) changes to a facility process not involved in the handling, processing or storage of licensed material
(5) minor changes to records management systems
(6) minor revisions or updates to training program content
(7) update of computer system software

Minor changes defined by the licensee's internal procedures would generally be discussed and approved at a meeting of the change originators and appropriate engineering evaluators based upon an internal review of the Configuration Management System evaluation.

4.1.2 Significant Changes

'Significant' changes are those that the licensee's change organization and the ISA analysis demonstrate to potentially have safety significance. The licensee's internal change evaluation procedures will be used to classify a change as being 'significant'. A significant change may require NRC pre-approval and, if required, application for a license in accordance with 10 CFR 70.34(a).

Six significant changes requiring NRC pre-approval are included in 10 CFR 70.62(c). NRC pre-approval is required if the change:

(1) creates a new <u>type</u> of accident sequence that could exceed the performance requirements of 10 CFR 70.61 <u>and</u> that was not analyzed in the ISA
(2) introduces new processes, technologies or control systems for which the licensee has no prior experience

(3) removes an IROFS listed in the ISA Summary without replacement by an equivalent IROFS
(4) alters an IROFS listed in the ISA Summary that is a sole IROFS
(5) is prohibited by license condition, order or exercise of the 10 CFR 70.72 change process

Other examples of significant changes that would generally require NRC pre-approval include:

(1) a change that involves a new fuel process or storage area
(2) a change that involves the relocation or decommissioning of a fuel processing area
(3) a change that involves ground breaking for a new fuel processing or fuel storage area, or the expansion of an existing fuel processing or fuel storage area
(4) a change that involves radiological safety or nuclear material control systems that may reduce the level of safety previously approved for an operation
(5) a change that indicates a potential increase in the monthly average of radioactive effluents
(6) a change that requires the addition of a radioactive effluent release point
(7) a change that results in a modification to the spacing requirements between fissile units
(8) change in the designation of a safety control as an IROFS
(9) a change that significantly modifies the facility emergency plan

Examples of significant changes that would <u>not</u> require NRC pre-approval include:

(1) a change that creates a new type of accident sequence determined by the ISA analysis to be of low safety significance (i.e. incapable of exceeding the performance requirements of 10 CFR 70.61 in an unmitigated state)and that would, therefore, not be included in the ISA Summary
(2) a change that creates a new accident sequence of a type that has been previously analyzed in the ISA and for which adequate IROFS are in place
(3) installation of digital monitoring system as a replacement for an analog monitoring system
(4) replacement of an IROFS by an equivalent or more robust IROFS in a double contingency situation (e.g. replacement of an administrative control by an engineered control or an active engineered control by a passive engineered control)
(5) change in operator procedures that enhance safety
(6) modification of any safety control that is neither identified by the licensee to be an IROFS nor listed in the ISA Summary

(7) a change to a facility operation that does not involve or impact the handling or storage of licensed material

5. RECORDS AND NRC REPORTING REQUIREMENTS

Records of all modifications or additions to facilities, processes, procedures and equipment must be maintained by the licensee [10 CFR 70.62(f)]. Records Management is closely interrelated with the Configuration Management System to ensure that licensee records are consistent with the facility design, plant configuration and facility documentation. Records should be maintained at the licensed facility for inspection by NRC personnel and should include, for example, internal evaluations of each change by plant engineering staff, licensee approvals and updates of the ISA and ISA Summary, if required. In addition to the facility records the licensee may be required to submit, brief tabulations of safety-significant changes implemented without NRC pre-approval are required to be annually reported to the NRC [10 CFR 70.62(d)].

Record Management is one of eight management measures a licensee must apply to IROFS to ensure their availability and reliability when required [10 CFR 70.4 and 70.62(d)]. When applied to IROFS, the Records Management measure is also used to ensure that the ISA, ISA Summary and process safety information are properly updated and that accurate and detailed records are maintained for each implemented change.

A licensee will generally not be required to describe its Records Management System in support of an application for a facility change. However, the NRC will seek assurances that the licensee does have in place a well-structured and robust system to create, index, store and maintain records and documents pertaining to a change.

5.1 Internal Licensee Records

Records of each modification or addition to the facility, processes, procedures and equipment must be maintained at the plant site. NUREG-1520 states that on-site documentation, including the ISA, should be updated within five business days of the date of implementation of the change. Records of all changes must be maintained until license termination and provide a written account of the change analysis including how a determination was made that the change did, or did not, require NRC pre-approval. The following documents should be retained at the facility:

- evaluations of changes (technical basis documents, engineering drawings)
- required limits and controls, if applicable
- internal management and engineering reviews
- updates to the ISA and ISA Summary and any process safety data
- approvals of changes (prior to implementation)

- analysis of how the licensee determined that NRC pre-approval of the change was, or was not, required
- records pertaining to implementation, testing and acceptance of completed work, detailed drawings, specifications, criticality safety evaluation, updated ISA and ISA Summary pages, *Facility Change Reports*, etc.

5.2 Reports to NRC for Pre-Authorized Changes

If a change requires NRC pre-approval and a license amendment is issued, no additional reporting requirements are required unless they are imposed as a license condition [10 CFR 70.32(b)(5)]. NRC pre-approved changes should be captured by the facility Configuration Management System to update the facility design basis. Changes to the ISA and the ISA Summary (if required) should also be made within the five-business day period specified in NUREG-1520.

5.3 Reports to NRC for Other Changes

Changes to facility systems that do not require NRC pre-approval and changes that affect IROFS listed in the ISA Summary must be reported to the NRC on an annual basis [10 CFR 70.72(d)]. Changes to the facility that could affect the health and safety of workers or the public or the control of licensed material, and that do not require NRC pre-approval are also to be reported annually.

Information should be submitted to the NRC by means of a *Facility Change Report*. Such reports should be limited to brief tabulations of the implemented changes. Detailed information on each change should not be included in the *Facility Change Report*, as it is maintained at the facility and is available for NRC review and inspection at any time.

A *Facility Change Report*, an example of which is presented in Appendix B, should contain the following information:

- change description (one sentence or a descriptive phase)
- process(es) impacted
- IROFS(s) or safety control system changed, if applicable
- date of change implementation
- ISA Summary updates (page or section references)

5.4 Timing of Submission of NRC Reports

Annual Report: An annual report on changes to the facility, equipment and processes that could affect either worker health and safety or the control of licensed material (including revised pages of the ISA Summary) is to be made within thirty days after the end of the calendar year during which the changes occurred. The annual *Facility Change Report* is, therefore, due on January 31st.

APPENDIX A

FACILITY CHANGE PROCESS – 10 CFR 70.72 REGULATIONS

§70.72 Facility changes and change process

(a) The licensee shall establish a configuration management system to evaluate, implement, and track each change to the site, structures, processes, systems, equipment, components, computer programs, and activities of personnel. This system must be documented in written procedures and must assure that the following are addressed prior to implementing the change:
    (1) The technical basis for the change
    (2) Impact of the change on safety and health or control of licensed material
    (3) Modifications to existing operating procedures including any necessary training or retraining before operation
    (4) Authorization requirements for the change
    (5) For temporary changes, the approved duration (e.g. expiration date) of the change, and
    (6) The impacts or modifications to the integrated safety analysis, integrated safety analysis summary, or other safety program information, developed in accordance with §70.62

(b) Any change to site, structures, processes, systems, equipment, components, computer programs, and activities of personnel must be evaluated by the licensee as specified in paragraph (a) of this section, before the change is implemented. The evaluation of the change must determine, before the change is implemented, if an amendment to the license is required to be submitted in accordance with §70.34

(c) The licensee may make changes to the site, structures, processes, systems, equipment, components, computer programs, and activities of personnel without prior Commission approval, if the change:
    (1) Does not:
        (i) Create new types of accident sequences that, unless mitigated or prevented, would exceed the performance requirements of §70.61 and that have not previously been described in the integrated safety analysis summary; or
        (ii) Use new processes, technologies or control systems for which the licensee has no prior experience
    (2) Does not remove, without at least an equivalent replacement of the safety function, an item relied on for safety that is listed in the integrated safety analysis summary
    (3) Does not alter any item relied on for safety, listed in the integrated safety analysis summary, that is the sole item preventing or mitigating an accident sequence that exceeds the performance requirements of §70.61; and
    (4) Is not otherwise prohibited by this section, license condition, or order.

(d)
    (1) For any changes that affect the list of items relied on for safety contained in the integrated safety analysis summary, as submitted in accordance with §70.65, but do not require NRC pre-approval, the licensee shall submit revised pages of the integrated safety analysis summary to NRC quarterly, within 30 days after the end of the calendar quarter during which the changes occurred.
    (2) For changes that require pre-approval under §70.72, the licensee shall submit an amendment request to the NRC in accordance with §70.34 and §70.65
    (3) A brief summary of all changes to the records required by §70.62(a)(2) of this part, that are made without prior Commission approval and revised pages to the integrated safety analysis summary, must be submitted to the NRC annually, within 30 days after the end of the calendar year during which the changes occurred.

(d) If a change covered by §70.72 is made, the affected on-site documentation must be updated promptly

(e) The licensee shall maintain records of changes to its facility carried out under this section. These records must include a written evaluation that provides the bases for the determination that the changes do not require prior Commission approval under paragraph (c) or (d) of this section. These records must be maintained until termination of the license.

APPENDIX B

FACILITY CHANGE REPORT EXAMPLE

ANNUAL FACILITY CHANGE REPORT

Licensee Name: _____ License Number: SNM-_____

Report for the 12-month Period Ending (MMDDYYYY): _____

NRC Docket Number: _____

Date of Report Submission: _____

SAFETY-SIGNIFICANT FACILITY CHANGES AND IROFS CHANGES

Change Number	Process Affected	Change Description	IROFS Affected[1]	ISA Summary Updates[2]

Notes: 1: Reference is to Items Relied on For Safety (IROFS) listed in the ISA Summary. If the change did not affect an IROFS listed in the ISA Summary, this column may be left blank. Otherwise, the Item(s) Relied on For Safety (IROFS) identified in the licensee ISA Summary that are affected should be referenced

2: Reference to page numbers and section numbers of the licensee ISA Summary. If the change did not affect an IROFS listed in the ISA Summary, this column may be left blank.